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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/713,098

11/14/2000

Constance H. Zlot

DX01051Q

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02/05/2002

DNAX RESEARCH INSTITUTE
LEGAL DEPARTMENT
901 CALIFORNIA AVENUE
PALO ALTO, CA 94304

EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 02/05/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/713,098

Applicant(s)
Zlot et al.

Examiner
G. R. Ewoldt

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Nov 28, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above, claim(s) 1-10, 13, 14, and 16-20 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 11, 12, and 15 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6, 11

20) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group IV, Claims 11, 12, and 15, is acknowledged. The traversal is on the grounds that Groups IV and XIII should be examined together as "the Examiner has not put forth a reason why it would be a serious burden to examine the claims of the above-identified groups together."

It is the Examiner's position that proper search burden has been established as set forth in the restriction requirement, mailed 10/24/01. In particular, claims drawn to products and claims drawn to methods comprise patentably distinct inventions requiring non-coextensive searches.

The requirement is made FINAL.

2. Claims 1-10, 13-14, and 16-20 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 11, 12, and 15 are being acted upon only as they recite an antibody binding site which specifically binds the polypeptide encoded by SEQ ID NO:2.

3. Claims 11 and 12 are objected to for the recitation of non-elected inventions, i.e., binding compounds specific for SEQ ID NOS:5 and 7.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 11, 12, and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody binding site which specifically binds the polypeptide encoded by SEQ ID NO:2, does not reasonably provide enablement for an antibody binding site which specifically binds at least 17 contiguous amino acids from the polypeptide encoded by SEQ ID NO:2.

Studies on the size of the antibody-antigen combining site using synthetic peptides have shown that antibodies recognize a maximum of 6 to 8 amino acid residues (Paul et al., 1999, page 657, column 2, paragraph 2). Additionally, many, if not most, antibodies display cross-reactivity (Paul et al., 1999, page 107, column 2, paragraph 5). Applicant has provided no evidence that a minimum of 17 amino acids are recognized by the claimed antibody nor has Applicant provided any evidence that the antibody cannot recognize and bind other molecules containing the antibody's undisclosed recognition sequence.


In view of the quantity of experimentation necessary to determine what amino acid sequences are actually bound, the lack of working examples disclosing the exact amino acid sequences bound, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention. See *in re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
February 2, 2002


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600